1

SYSTEM AND METHOD FOR DETERMINING ARTERIAL COMPLIANCE AND STIFFNESS

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to a system, method and apparatus for determining arterial compliance and stiffness. In particular, the invention relates to a non-invasive quantitative system for calculating arterial elastic recoil pressure for vascular flow, arterial compliance, stiffness and arterial blood flow and resistance compliance. The method steps consist of modeling and combining arterial behavior from signature waveform flow velocities such as peak-systolic and end-diastolic arterial blood flow velocities and systemic blood pressure. The method determines the artery elastic recoil pressure for vascular blood flow as an Arterial Compliance Index ("ACI"), which correlates to blood pressure, artery distension, stiffness, arterial blood flow and resistance and is compared to a baseline index for a particular artery in issue.

2. Description of Related Art

The term elastic recoil pressure is used to describe the pressure exerted by the arterial walls when they recoil. Arterial elastic recoil pressure results from the distension and recoil of the artery necessary to regulate and maintain blood 25 pressure and continued arterial blood flow.

The term arterial compliance is used to describe the flexibility of the arterial walls. Arterial compliance or distension results in the capacity of the artery to maintain blood flow by moving more volume with less pressure or distending more 30 with less force applied.

The term arterial stiffness is used to describe the rigidity of the arterial walls. Arterial stiffness results in the incapacity of the artery to maintain blood flow by moving less volume with more pressure or distending less with more force applied.

The terms arterial blood flow and resistance are used to describe the flow and resistance to blood flow across the systemic arterial vasculature. Arterial blood flow resistance results in the incapacity of the systemic arterial vasculature to support blood flow by either increasing the arterial elastic 40 recoil pressure thus reducing the pressure difference within the artery that pushes the blood or by increasing the force that opposes the blood flow through the vascular resistance.

Arterial compliance and stiffness assist in assessing soft and hard plaque formation on the artery walls, arterial inflammation, narrowing of arteries, arterial stenosis, local arterial function, arterial blood flow and resistance, systemic pressure and circulation in the peripheral arterial system, central pressure and circulation in the aorta. Also, Arterial compliance and stiffness can be associated with changes in heart rate and changes in the chemistry of body fluids naturally occurring or through the use of substances for medical or non-medical purposes. Thus, arterial compliance and stiffness are critical parameters for predicting and diagnosing both vascular and cardiovascular problems.

Current methods of measuring arterial stiffness are technically demanding, time consuming, costly, or limited in scope. It is therefore desirable to have an alternative comprehensive method which includes arterial blood flow velocities, elastic recoil pressure and systemic blood pressure, which can be 60 used for any particular artery in issue and which can diagnose artery distension, stiffness, arterial blood flow and resistance in real time within the routine clinical setting.

Arterial compliance and stiffness depend on the functioning of muscle cells, elastin and collagen within the artery walls. These structural elements support the pressure of blood exerted on the artery wall when distended. Arteries distend

2

and recoil in order to regulate and maintain blood pressure and continuous blood flow through the arterial system.

Presently known non-invasive methods and indices for measuring and quantifying arterial compliance and stiffness have several limitations in measurement and interpretation. For example, current methods and indices for measuring and quantifying arterial compliance and stiffness require expensive equipment, a high level of technical expertise and are often impractical or limited in scope within the routine clinical setting.

At this time, pulse wave velocity (PWV) analysis is the standard for diagnosing regional arterial stiffness. Pulse wave velocity is the speed at which a forward pressure wave is transmitted from the aorta or other major artery through the vascular tree. It is calculated by measuring the time it takes for the arterial waveform to pass between two points a measured distance apart.

The flow of blood through the arterial vasculature is influenced by the stiffness and elasticity of the vessel walls. With varying blood pressure and vascular resistance: The stiffer the arterial walls, the lower the elastic recoil pressure and the higher the blood flow. In elastic vessels, the higher the elasticity of the arterial walls, the higher the elastic recoil pressure and the lower the blood flow.

A current method to determine arterial blood flow resistance is based on what is called the Resistive Index ("RI") that relies only on blood flow velocities. The RI alone is inadequate to accurately assess arterial compliance, stiffness, flow and resistance.

30 Blood flow velocities can be determined from the arterial pulse waveforms along a vascular segment. Doppler ultrasound, Magnetic resonance imaging, positron emission tomography, Photoplethysmography, laser Doppler imaging, and laser speckle contrast imaging are used to measure blood 35 flow velocities.

Stiff arteries result in higher systolic pressure, lower diastolic pressure and other blood pressure disorders because there is less elastic recoil to regulate the blood pressure. Thus, systolic and diastolic blood pressure, are both also important factors in predicting cardiovascular risk. Increased pulse pressure, increased heart rate at rest, and increased pulse wave velocity may be markers of underlying vascular disease or strong cardiovascular risks.

Pulse pressure is the difference between systolic and diastolic pressures, and depends on the cardiac output, large-artery stiffness and wave reflection. Thus the difference between systolic and diastolic pressure, that is the pulse pressure, will be expected to vary as the rigidity of the arterial walls. However, pulse pressure alone is inadequate to assess arterial stiffness accurately.

Thus, it is desirable to achieve an improved system, method and apparatus that combines the diagnostics of arterial flow velocities and systemic blood pressure readings for a particular artery in order to accurately determine the extent of artery distension and stiffness in real time and enable a comparison of a subject's artery distension and stiffness with a baseline index for the particular artery in issue.

SUMMARY OF THE INVENTION

The inventive method combines the velocities of blood flowing within an artery at points in time and systemic blood pressure to create a system and method that calculates an Arterial Compliance Index ("ACI"). The ACI or arterial elastic recoil pressure correlates to blood pressure, artery distension, stiffness, arterial blood flow and resistance and is compared to a Baseline Index ("BI") for the particular artery type